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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/966,447	09/28/2001	David Christian Lentz	CRD0957USNP	2148

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EXAMINER	
RYCKMAN, MELISSA K	
ART UNIT	PAPER NUMBER
3773	

NOTIFICATION DATE	DELIVERY MODE
05/10/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	09/966,447	LENTZ ET AL.	
	Examiner	Art Unit	
	MELISSA RYCKMAN	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 February 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,18 and 20-34* is/are pending in the application.

4a) Of the above claim(s) *18 and 20-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/11/11, 3/11/11*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to claims filed 2/28/11.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gifford, III et al. (U.S. Patent No. 5,904,697) in view of Tuch (U.S. Patent No. 5,624,411), Rakos et al. (U.S. Patent No. 6,015,432) and Shannon (U.S. Patent No. 5,928,279).

Gifford teaches a device for joining substantially tubular organs in a living organism, comprising: an anastomosis device (as clearly seen in Figs. 42A-42D) for connecting a graft vessel to a target vessel such that the two vessels are in fluid communication, the anastomosis device including a fastening flange and a plurality of staples connected to the fastening flange and having sharpened ends with barbs, the fastening flange comprising a single wire ring structure having a substantially sinusoidally shaped configuration for reduced profile delivery and configured to have a substantially flat profile upon deployment and the plurality of staples being configured to spring from a restraint position to a position substantially perpendicular to the ring structure and finally to an everted loop position through the graft vessel and target

vessel, the plurality of staples extending from the wire ring structure in the same direction as the substantially sinusoidally shaped configuration and extending substantially beyond the wire ring for eversion.

Gifford is silent regarding a biocompatible vehicle affixed to the device, however Tuch teaches an vasculature device wherein the device includes a primer layer affixed to at least a portion of the anastomosis device (underlayer col. 2, ll. 51, with a drug/polymeric mixture on top of the underlayer, col.2, ll. 53-56) the primer layer and the polymer are similar in chemical composition (col. 10, ll. 48 and 56 with col. 2, ll. 53-56), and biocompatible vehicle (col. 2, ll. 50-67) being made from polymer materials for carrying drugs to facilitate healing and or sealing (see col. 3). Tuch teaches a top coating to delay the release of drugs (col. 3, ll. 15,16 and 29). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Gifford with a primer layer and biocompatible vehicle including a therapeutic agent as taught by Tuch in order to carry drugs to facilitate healing and or sealing of the anastomosis site. It would have been obvious to one of ordinary skill in the art to delay the release of the drug as this make the drug last longer in the body one it is released, which would help with healing.

Tuch also teaches a polymeric coating that controls the rate of the release of a drug (col. 2, ll. 50-67) but does not mention the drug to be rapamycin. However, Rakos teaches using rapamycin (col. 4, ll. 12). It would have been obvious to one of ordinary skill in the art to use the rapaycin of Rakos with Tuch and Gifford as rapamycin helps to enhance endotheliztion of the prosthesis (col. 4, ll. 13,14 Rakos).

The combination of Gifford, Tuch and Rakos does not disclose the anastomosis device comprising the polymeric matrix and/or drugs as claimed, Shannon teaches using a coating on a stent comprising many polymers including PVDF and FEP (col. 9, ll. 11-20).

Shannon is silent regarding combining the polymers, however it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the biocompatible plastics forming a copolymer that is a known biocompatible polymer (as specified by Shannon, col. 9, ll. 20). Regarding the amounts of PVDF and FEP in the compound, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have the compound include 55-65% by weight of PVDF, and 45-35% by weight of FEP, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch,* 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Shannon discloses the claimed invention except for HFP. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use HFP, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Response to Arguments

Applicant's arguments filed 2/28/11 have been fully considered but they are not persuasive. The applicant argues none of the references teach using HFP as a coating,

however Shannon teaches using polytetrafluoroethylene (PTFE) (col. 9, ll. 15), tetrafluoroethylene is used to produce hexafluoropropylene (HFP). Included in the above rejection is: Shannon discloses the claimed invention except for HFP. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use HFP, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416. The examiner points to the current application which lists a variety of suitable compounds including HPF (current specification page 23, line 15-19) there is reasoning to specifically use HPF.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA RYCKMAN whose telephone number is (571)272-9969. The examiner can normally be reached on a flexible schedule, email address is melissa.ryckman@uspto.gov.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571)-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MKR
/Melissa Ryckman/
Examiner, Art Unit 3773

/Darwin P. Erezo/
Primary Examiner, Art Unit 3773